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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,903	07/11/2000	Heather J. Jordan	0942.4450001	1446
26111	7590	05/18/2005		EXAMINER
		STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005		SISSON, BRADLEY L
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/613,903	JORDAN, HEATHER J.	
	Examiner Bradley L. Sisson	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 February 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 43,44,46,48-50,52-57,59-61,63 and 64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 43,44,46,48-50,52-57,59-61,63 and 64 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 February 2005 has been entered.

Specification

2. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states:

All publications, patent applications and patents cited herein are fully incorporated by reference herein in their entirety.

Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents.

3. Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent,

application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found.
(Emphasis added)

As set forth In *Ex parte Raible*, 8 USPQ2d 1707, (BPAI, 1998)

The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree

* * *

We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144, (CCPA 1973).

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Response to argument

4. At pages 7-8 of the response received 28 February 2005, hereinafter the response, applicant's representative asserts that the objection to the specification should be withdrawn, asserting *inter alia* "different types of subject matter have distinct incorporation by reference requirements." Said representative asserts further that the cited decision is applicable only to matters of anticipation and not to matters of 112, first paragraph.

5. The above argument has been fully considered and has not been found persuasive. While general bibliographic citations of documents incorporated or not incorporated by reference can

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serve to teach the level of skill in the art and/or the state of the art at the time of filing, such general teachings, without more, do not rise to the level of satisfying the requirements of written description and/or best mode if that which is being claimed is to be found therein and was not properly incorporated by reference. While an applicant is urged not to repeat that which is well known in the art, disclosure of specific starting materials and reaction conditions are recognized as being essential to satisfying the enablement requirement of 35 USC 112, first paragraph.¹ As set forth above, applicant can satisfy some of these aspects through incorporation by reference. In so doing, however, the host document must identify what information is being incorporated and where it is to be found. In the instant disclosure, however, the specification does not teach both what material is to be incorporated and where it is to be found. Accordingly, applicant

¹ As set forth in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001:

“[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.” *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) (“[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.”).

“Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that ‘a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.’) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

“It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

cannot rely upon the disclosures for satisfaction of the requirements of 35 USC 112, first paragraph.

Claim Objections

6. Claim 52 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 43 sets that the range in size of the fragments is to be from “about 25 kb to about 100 bp,” however, claim 52 stipulates that the fragments of the composition are to “differ in length by increments of about 1,000 basepairs.” It is not possible to have fragments of either 25 KB or 100 BP and at the same time vary the fragment lengths in units of 1,000. Accordingly, such a limitation effectively broadens the scope of claim 43, not further limit it.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 43, 44, 46, 48-50, 52-56, 59-60, 63, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Life Technologies Catalogue (1995-1996) in view of Stratagene Cloning Systems Catalog (Stratagene; 1993).

11. Life Technologies Catalogue discloses for sale a variety of DNA ladders. As seen at page 14-2, the ladder can be comprised of repeating units of 10 bp, and starting from an oligonucleotide of only 10 bp and can go to and beyond 100 bp. Also seen for sale are DNA ladders that are based on repeating units of 50 bp, 100 bp, 123 bp, 1 kb, etc.

12. Life Technologies Catalogue discloses that the concentration of some fragments in some ladders has been adjusted so that certain desired marker(s) appear brighter than others (a limitation of claims 63 and 64). It is also readily apparent that the individual bands in the 1 kb ladder also appear to be at the same relative intensity in the photo of stained bands in a gel subsequent to electrophoresis (see page 14-4). As seen in the caption for the 1 kb ladder, the

DNA fragments can be visualized when stained with ethidium bromide (a limitation of claim 55).

13. Life Technologies do not teach of a ladder that has an upper limit of 25 kb.
14. Stratagene, page 122, teaches DNA ladders that range from about 400 bp to about 48 kb.

In the event that applicant considers the prior art as not teaching the generation of bands that will have substantially the same intensity, it is the position that such a property is the result of routine optimization and does not rise to the level of a patentable distinction. It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955):

Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. *In re Dreyfus*, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52; *In re Waite et al.*, 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. *In re Swenson et al.*, 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; *In re Scherl*, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. *In re Sola*, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; *In re Normann et al.*, 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; *In re Irmscher*, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Swain et al.*, 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; *Allen et al. v. Coe*, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added)

15. In view of the preceding remarks, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have developed any of a variety of DNA ladders for

use in an electrophoresis assay and to have adjusted the relative concentrations of the bands such that the intensities of any one or all bands was the same or more intense than others as the ordinary artisan desired. In view of the well-developed state of the art, and the broad usage of such markers, the ordinary artisan would have been both highly motivated and would have had a most reasonable expectation of success.

16. Claims 57 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Life Technologies Catalogue (1995-1996) in view of Stratagene Cloning Systems Catalog (Stratagene; 1993) as applied to claims 43, 44, 46, 48-50, 52-56, 59-60, 63 and 64 above, and further in view of Lee (US patent 5,268,568).

17. See above for the basis of the rejection as it pertains to the disclosures of Life technologies Catalogue 1995-1996, and Stratagene.

18. Neither Life Technologies Catalogue 1995-1996 nor Stratagene disclose the use of the dye mixture.

19. Lee discloses that just a dye mixture comprising bromophenol blue or xylene cyanol FF is routinely added to DNA samples to be subjected to electrophoresis.

20. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the DNA ladders of Life Technologies such that a dye comprising bromophenol blue was included given its common usage in electrophoresis of DNA samples. As evidenced by the pictures of the ladders offered for sale by Life technologies, the pictures are of ladders separated via electrophoresis. Accordingly, the addition of a dye to a ladder known to be used in electrophoresis would have been an obvious combination, as it would have facilitated the ordinary artisan in determining the degree samples have been subjected to electrophoresis. In

view of the commercial availability of DNA ladders, a kit comprising same would have been an obvious commercial expedient, requiring little, if any, additional effort on the part of the ordinary artisan.

21. For the above reasons, and in the absence of convincing evidence to the contrary, claims 57 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Life Technologies Catalogue (1995-1996) in view of Stratagene Cloning Systems Catalog (Stratagene; 1993) as applied to claims 43, 44, 46, 48-50, 52-56, 59-60, 63 and 64 above, and further in view of Lee (US patent 5,268,568).

Conclusion

22. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

23. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
16 May 2005